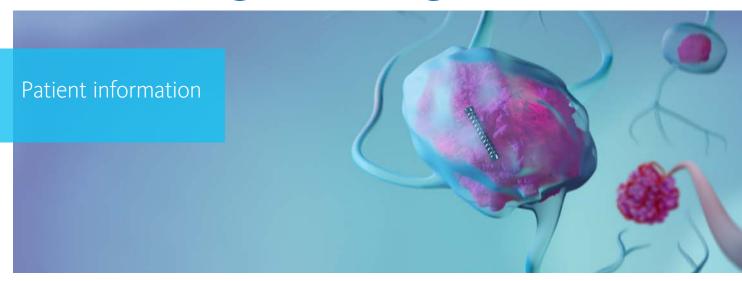


Marking and localisation of suspicious lymph nodes

Sentimag® – Magseed®



Marking and localisation of your suspicious lymph node

During examination, your doctor has found one or more suspicious lymph nodes that might contain breast cancer cells (metastases). These should be removed during your breast surgery. Your doctor recommends the use of Magseed® and the Sentimag® magnetic localisation system to mark the suspicious lymph node(s) over the period of the entire therapy, so that your doctor can safely locate and remove the suspicious lymph node(s) after the end of therapy during the subsequent breast surgery.

The procedure

In order to be able to clearly identify the lymph node(s) that is/are classified as suspicious after therapy, your doctor uses a guide and marker to mark suspicious lymph nodes for safe removal.

The Magseed® marker is a 1 x 5 mm tiny seed made of medical stainless steel designed for this purpose. Using an introducer needle under ultrasound or X-ray guidance, it is placed into the suspicious lymph node and can remain there for an unlimited time. The placement is usually carried out before the systemic treatment.

The implanted Magseed® cannot be felt and does not cause any pain once in place.

During breast surgery, once you have fallen asleep under anaesthesia, the doctor will scan your skin with the Sentimag® probe. The probe emits a magnetic field, so that the Magseed® marker in the suspicious lymph node(s) become(s) temporarily magnetic and generate(s) a signal. In this way, the exact localisation of the suspicious lymph node(s) is detected with the Sentimag® probe and the suspicious lymph nodes(s) can be removed. The lymph nodes are then sent to the pathology laboratory for analysis.



Magseed® causes a visual artefact with a radius of up to about 4.1 cm

Benefits

The Magseed® marker is an established technique that has been used in more than 65,000 cases to date. It enables doctors to safely mark and accurately localise the seed during surgery, as well as providing flexibility and simplified procedures, resulting in less pain and stress for patients.

An alternative is to mark suspicious lymph nodes with a clip and/or (additional) guide wire. In contrast to the Magseed® marker, clips cannot be detected with a probe and are difficult to find before and during the surgery using imaging. In addition, clips and the guide wire carry a certain risk of migrating into the surrounding tissue. The guide wire can cause pain during breathing and movement in some patients.

Risks

Potential complications of the Magseed® placement may include, but are not limited to: haematoma, haemorrhage, infection, adjacent tissue injury, pneumothorax, allergic reaction and pain.

Magseed® is secured in the introducer needle with bone wax. Some reaction to bone wax may occur, such as an allergic reaction or reactions to foreign bodies (e.g. granulomas). Magseed® contains nickel (0.23%). Compared to normal medical stainless steel, Magseed® contains 10-15 x less nickel. You must tell your doctor if you have been diagnosed with a nickel intolerance. Caution should be exercised with using Magseed® on patients with prostheses so as to not puncture the prosthesis during placement.

Non-clinical tests have shown that Magseed® is conditionally MRI-safe. Under normal MRI conditions (your doctor knows this in greater detail), an MRI scan is safe for patients with Magseed®.

There is no risk of Magseed® overheating (max. 5.3°C). Like a guide wire/clip, Magseed® also impacts MRI examinations. Magseed® causes a visual artifact up to about 4.1 cm away from the Magseed®. You are not expected to have an MRI scan of the marked region or surrounding tissue while the Magseed® marker is in your lymph node. Otherwise, your doctor will decide before placing Magseed® whether an MRI is still feasible or select an alternative suitable imaging technique.

The Sentimag® probe should not be placed within 15 mm of any part of an operating pacemaker. Your doctor will take this into account.

Indication and usage

The magnetic localisation system Magseed® and Sentimag® is used in cancer patients for long-term marking and locating lymph nodes, before these are surgically removed.

Magseed® marker is intended only for use with the Sentimag® device.

Contraindications

- 1. Magseed® marker is not intended for use in the central nervous system, circulatory system, heart, eyes or brain.
- 2. Magseed® must not be placed in a tissue site with clinical evidence of infection.

The magnetic localisation system Magseed® and Sentimag® consists of two parts:

- 1. Magseed® a magnetic marker implanted into the tissue.
- 2. Sentimag® a probe that can detect Magseed® in the body by magnetism.

Glossary of medical terms

MRI (Magnetic Resonance Imaging)

A procedure using magnetic fields and radio waves to form an image of structures inside the body, e.g. in order to identify recurrences.

Metastasis

Settlement of abnormal cells in a part of the body that is distant from the source of the disease. Most of the time such procrastination takes place via blood or the lymph system in connection with cancer.

Pneumothorax

Abnormal/pathological air accumulation in the chest.

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